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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,225	12/22/2003	Fritz Sacher	1/1444US	7664

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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/743,225	SACHER ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 08 September 2005 is acknowledged and has been entered. Claims 1-19 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly recited limitation "the effective amount adapted to effect in the patient a Lasser Doppler Flowmetry frequency increase between about 127 to about 194 in the 10-37 kHz range after 3 weeks from the beginning of treatment" (recited within each of independent claims 1-6) is deemed new matter. Applicants state that support for this phrase limitation is found in Table 3 (page 12) of the instant specification. However, Table 3 does not provide literal support for the approximate (i.e., "about") frequency range instantly claimed.

Claim Rejections - 35 USC § 102

Claims 1-19 stand rejected under 35 U.S.C. 102(b) as being anticipated by Esperester et al. (WO 01/28363) for the reasons set forth in the previous Office action which are restated below.

Esperester et al. teaches a method of treating or prevent various venous insufficiencies of the lower extremities via orally administering (e.g., in tablet or capsule by the addition of one or more excipients) to a subject in need thereof an effective amount of an aqueous red vine leaf extract, including within the instantly claimed amount (and/or daily dosage) ranges of red vine leaf extract and flavonoids therein, whereby the red leaf extract is prepared via the instantly claimed steps (see entire document including page 1, line 21 – page 6, line 8, and claims). Please note that the administration of the aqueous red vine leaf extract taught by Esperester et al. would inherently provide the in vivo functional effects instantly claimed including those drawn to enhancing blood microcirculation and/or oxygen supply of the skin of the low extremities (as well as those drawn to preventing the various recited venous insufficiency conditions). In addition, please note that the administered amount of aqueous red vine leaf extract taught by Esperester et al. would inherently provide the newly recited non-positively claimed effect with respect to Laser Doppler Flowmetry frequency increase in such a subject (if measured thereby) - i.e., if measured, a Laser Doppler Flowmetry frequency increase to within the approximate kHZ range instantly claimed would inherently occur in a subject who was administered the amount of aqueous red vine leaf extract taught by Esperester et al. for three weeks.

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 1-19 stand rejected under 35 U.S.C. 102(e) as being anticipated by Esperester et al. (US 6,485,727) for the reasons set forth in the previous Office action which are restated below.

As set forth in the previous Office action, it is noted that the applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Esperester et al. teaches a method of treating or prevent various venous insufficiencies of the lower extremities via orally administering (e.g., in tablet or capsule by the addition of one or more excipients) to a subject in need thereof an effective amount of an aqueous red vine leaf extract, including within the instantly claimed amount (and/or daily dosage) ranges of red vine leaf extract and flavonoids therein, whereby the red leaf extract is prepared via the instantly claimed steps (see entire document including col 1, line 24 – col 4, line 13; and claims). Please note that the administration of the aqueous red vine leaf extract taught by Esperester et al. would inherently provide the in vivo functional effects instantly claimed including those drawn to enhancing blood microcirculation and/or oxygen supply of the skin of the low extremities (as well as those drawn to preventing the various recited venous insufficiency conditions). In addition, please note that the administered amount of aqueous red vine leaf extract taught by Esperester et al. would inherently provide the newly recited non-positively claimed effect with respect to Laser Doppler Flowmetry frequency increase in such a subject (if measured thereby) - i.e., if measured, a Laser Doppler Flowmetry frequency increase to within the approximate kHZ range instantly claimed would inherently occur in a subject who was administered the amount of aqueous red vine leaf extract taught by Esperester et al. for three weeks.

Therefore, the reference is deemed to anticipate the instant claims above.

Applicants' arguments concerning the above USC 102 rejections have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that the cited references do not disclose or even suggest the newly recited claim limitation with respect to providing an approximate Laser Doppler Flowmetry frequency increase range within such a patient, as measured after three weeks of administration. However, as discussed above, please note that the administered amount of aqueous red vine leaf extract taught by either of the Esperester et al. references would inherently provide the newly recited non-positively claimed effect with respect to Laser Doppler Flowmetry frequency increase in such a patient (if measured thereby) - i.e., if measured, a Laser Doppler Flowmetry frequency increase to within the approximate kHZ range instantly claimed would inherently occur in a patient who was administered the amount of aqueous red vine leaf extract taught by Esperester et al. for three weeks.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Esperester et al. (WO 01/28363) or over Esperester et al. (US 6,485,727), in view of the admitted state of the art.

The two Esperester et al. references are relied upon for the reasons discussed *supra*, both of which appear to anticipate the instantly claimed invention (as set forth above).

However, in the alternative (if not anticipated), it would clearly have been obvious to one of ordinary skill in the art at the time the claimed invention was made to assess the therapeutic progress of a subject suffering from venous insufficiency at one or more time periods during such treatment (such as half-way through such treatment - i.e., three weeks through the overall six weeks of treatment taught by each of the Esperester et al. references) via the conventional use of Laser Doppler Flowmetry since Applicants readily admit (and as notoriously well recognized in the art), the application of the Laser Doppler technique is well known in the prior art to be useful as an effective means for measuring and assessing such venous disorders (see, e.g., paragraph bridging pages 1-2 of the instant specification). Accordingly, the result-effective adjustment of this type of conventional working conditions (and/or providing an effective dosage amount of the reference aqueous red vine leaf extracts to a subject suffering from venous insufficiency so as to be within a therapeutic Laser Doppler frequency range measurement after a certain duration of such treatment) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over either of the cited references, especially in the absence of evidence to the contrary.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher R. Tate
Primary Examiner
Art Unit 1654